

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of: Gregg B. Morin et al.

Art Unit: 1635

For: CANCER THERAPY USING THE TELOMERASE  
PROMOTER

Examiner: Richard A. Schnizer, Ph.D.

**INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 CFR § 1.98(d)**

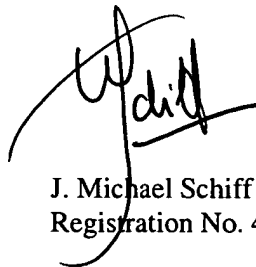
Commissioner for Patents  
Alexandria, VA 22313

Dear Sir:

The information listed in the accompanying form PTO-1449 may be material to examination of this application and are submitted in compliance with the duty of disclosure under 37 CFR § 1.56. The Examiner is requested to make this information of record in the application.

Copies of the information are not provided herewith, but were previously filed in parent application 09/675,321, to which this application claims priority under 35 USC § 120. The Examiner is respectfully directed to the file for application 09/675,321 to access the information listed on the accompanying form PTO-1449. This is in compliance with the provisions of 37 CFR § 1.98(d).

This Information Disclosure Statement is not to be construed as a representation that a full search for relevant information has been made, or that the information listed on the accompanying PTO-1449 is material to patentability of the claimed invention under 37 CFR § 1.56(b).



J. Michael Schiff  
Registration No. 40,253

GERON CORPORATION  
230 Constitution Drive  
Menlo Park, CA 94025  
Telephone: (650) 473-7715  
Fax: (650) 473-8654

September 29, 2003

<b>Form 1449</b> (modified)  <b>Information Disclosure</b>  <b>Statement By Applicant</b>  (Use Several Sheets if Necessary)	Docket: 019/246P  Title: Telomerase Reverse Transcriptase Transcriptional Regulatory Sequences Inventors: Morin, G., et al.  Filing Date: 04 Feb 1999 Group: 1642
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**U.S. Patent Documents**

Examiner Initial	Ref.	Patent No.	Filing Date	Issue Date	Class/ Subclass	Inventors:	Title:
	A	5,416,017	25 Mar 1993	16 May 1995	435/240.2	Burton, F.H., et al.	Cholera Toxin Gene Regulated by Tissue-Specific Promoters
	B	5,631,236	26 Aug 1993	20 May 1997	514/44	Woo, S., et al.	Gene Therapy for Solid Tumors, Using a DNA Sequence Encoding HSV-Tk or VZV-Tk
	C	5,728,379	7 Jun 1995	17 Mar 1998	424/93.2	Martuza, R., et al.	Tumor or Cell Specific Herpes Simplex Virus Replication
	D	5,998,205	1 Jul 1997 (pub. 6 Jun 1996)	7 Dec 1999	435/325	Hallenbeck, P.L., et al.	Vectors for Tissue-Specific Replication
	E	6,093,809	6 May 1997	25 Jul 2000	536/23.5	Cech, T., et al.	Telomerase

**Foreign Patent or Published Foreign Patent Application**

Examiner Initial	Ref.	Document No.	Publ. Date	Jurisdiction	Title:	Translation	
						Yes	No
	F	WO 98/07838	26 Feb 1998	PCT	Higher Animal Telomerase Protein and Gene Encoding the Same	X summary	X
	G	WO 98/14592	9 Apr 1998	PCT	Telomerase Reverse Transcriptase		
	H	WO 98/14593	9 Apr 1998	PCT	Human Telomerase Catalytic Subunit		
	I	WO 98/21343	22 May 1998	PCT	Genes Encoding Telomerase Proteins		
	J	WO 98/37181	27 Aug 1998	PCT	Telomerase Catalytic Subunit Gene and Encoded Protein		
	K	WO 99/01560	1 Jan 1999	PCT	Vertebrate Telomerase Genes and Proteins and Uses Thereof		
	L	WO 99/33998	8 Jul 1999	PCT	Regulatory DNA Sequences of the Human Catalytic Telomerase Sub-Unit Gene, Diagnostic and Therapeutic Use Thereof	X partial	X
	M	WO 99/38964	5 Aug 1999	PCT	Promoter Regions of the Mouse and Human Telomerase RNA Component Genes		

Examiner	Date Considered

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 PTO-1449 — Page 1

Form 1449 (modified)

Docket: 019/246P

U.S.S.N. 09/244,438

## Information Disclosure

## Statement By Applicant

(Use Several Sheets if Necessary)

Title: Telomerase Reverse Transcriptase Transcriptional Regulatory Sequences

Inventors: Morin, G., et al.

Filing Date: 04 Feb 1999

Group: 1642

## Other Documents

Examiner Initial	Ref.	Author, Title, Date, Source
	N	Berenstein, M., et al., "Different efficacy of <i>in vivo</i> herpes simplex virus thymidine kinase gene transduction and ganciclovir treatment on the inhibition of tumor growth of murine and human melanoma cells and rat glioblastoma cells", <i>Cancer Gene Therapy</i> , 6(4):358-366 (1999)
	O	Bi, W., et al., "An HSVtk-mediated local and distant antitumor bystander effect in tumors of head and neck origin in athymic mice", <i>Cancer Gene Therapy</i> , 4(4):246-252 (1997)
	P	Brand, K., et al., "Tumor cell-specific transgene expression prevents liver toxicity of the adeno-HSVtk/GCV approach", <i>Gene Therapy</i> , 5:1363-1371 (1998)
	Q	Cong, YS., et al., "The Human Telomerase Catalytic Subunit hTERT: Organization of the Gene and Characterization of the Promoter", <i>Human Molecular Genetics</i> , 8(1):137-142 (1999)
	R	Devereux, T.R., et al., "DNA Methylation Analysis of the Promoter Region of the Human Telomerase Reverse Transcriptase ( <i>hTERT</i> ) Gene", <i>Cancer Res.</i> , 59:6087-6090 (15 Dec 1999)
	S	Eishami, A.A., et al., "The effect of promoter strength in adenoviral vectors containing herpes simplex virus thymidine kinase on cancer gene therapy <i>in vitro</i> and <i>in vivo</i> ", <i>Cancer Gene Therapy</i> , 4(4):213-221 (1997)
	T	Horikawa, I., et al., "Cloning and Characterization of the Promoter Region of Human Telomerase Reverse Transcriptase Gene", <i>Cancer Res.</i> , 59:826-830 (15 Feb 1999)
	U	Klatzmann, D., et al., "A Phase I/II Dose-Escalation Study of Herpes Simplex Virus Type I Thymidine Kinase "Suicide" Gene Therapy for Metastatic Melanoma", <i>Human Gene Therapy</i> , 9:2585-2594 (20 Nov 1998)
	V	Klatzmann, D., et al., "A Phase I/II Study of Herpes Simplex Virus Type I Thymidine Kinase "Suicide" Gene Therapy for Recurrent Glioblastoma", <i>Human Gene Therapy</i> , 9:2595-2604 (20 Nov 1998)
	W	Li, P.-X., et al., "Differential chemosensitivity of breast cancer cells to ganciclovir treatment following adenovirus-mediated herpes simplex virus thymidine kinase gene transfer", <i>Cancer Gene Therapy</i> , 6(2):179-190 (1999)
	X	Princen, F., et al., "Repeated cycles of retrovirus-mediated HSVtk gene transfer plus ganciclovir increase survival of rats with peritoneal carcinomatosis", <i>Gene Therapy</i> , 5:1054-1060 (1998)
	Y	Robertson, M.W., III, et al., "Use of a tissue-specific promoter for targeted expression of the herpes simplex virus thymidine kinase gene in cervical carcinoma cells", <i>Cancer Gene Therapy</i> , 5(5):331-336 (1998)
	Z	Shand, N., et al., "A Phase 1-2 Clinical Trial of Gene Therapy for Recurrent Glioblastoma Multiforme by Tumor Transduction with the Herpes Simplex Thymidine Kinase Gene Followed by Ganciclovir", <i>Human Gene Therapy</i> , 10:2325-2335 (20 Sep 1999)
	AA	Siders, W.M., et al., "Melanoma-specific cytotoxicity induced by a tyrosinase promoter-enhancer/herpes simplex virus thymidine kinase adenovirus", <i>Cancer Gene Therapy</i> , 5(5):281-291 (1998)
	AB	Smiley, W.R., et al., "Establishment of Parameters for Optimal Transduction Efficiency and Antitumor Effects with Purified High-Titer HSV-TK Retroviral Vector in Established Solid Tumors", <i>Human Gene Therapy</i> , 8:965-977 (20 May 1997)
	AC	Sterman, D.H., et al., "Adenovirus-Mediated Herpes Simplex Virus Thymidine Kinase/Ganciclovir Gene Therapy in Patients with Localized Malignancy: Results of a Phase I Clinical Trial in Malignant Mesothelioma", <i>Human Gene Therapy</i> , 9:1083-1092 (1 May 1998)
	AD	Su, H., et al., "Tissue-specific expression of herpes simplex virus thymidine kinase gene delivered by adeno-associated virus inhibits the growth of human hepatocellular carcinoma in athymic mice", <i>Proc. Natl. Acad. Sci. USA</i> , 94:13891-13896 (Dec 1997)
	AE	Takakura, M., et al., "Cloning of Human Telomerase Catalytic Subunit (hTERT) Gene Promoter and Identification of Proximal Core Promoter Sequences Essential for Transcriptional Activation in Immortalized and Cancer Cells", <i>Cancer Res.</i> , 59:551-557 (1 Feb 1999)
	AF	Wick, M., et al., "Genomic organization and promoter characterization of the gene encoding the human telomerase reverse transcriptase (hTERT)", <i>Gene</i> , 232:97-106 (1999)
	AG	Wildner, O., et al., "Adenoviral vectors capable of replication improve the efficacy of HSVtk/GCV suicide gene therapy of cancer", <i>Gene Therapy</i> , 6:57-62 (1999)
	AH	Wildner, O., et al., "Therapy of Colon Cancer with Oncolytic Adenovirus Is Enhanced by the Addition of Herpes Simplex Virus-thymidine kinase", <i>Cancer Research</i> , 59:410/413 (1999)
	AI	Wu, K.-J., et al., "Direct activation of <i>TERT</i> transcription by c-MYC", <i>Nature Genetics</i> , 21:220-224 (Feb 1999)

Examiner	Date Considered

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PTO-1449 — Page 2

<b>Form 1449</b> (modified)  <b>Information Disclosure</b>  <b>Statement By Applicant</b>  (Use Several Sheets if Necessary)	Docket: 019/246P  Title: Telomerase Reverse Transcriptase Transcriptional Regulatory Sequences Inventors: Morin, G., et al.  Filing Date: 04 Feb 1999 Group: 1642
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Examiner Initial	Ref.	Author, Title, Date, Source
	AJ	Yang, L., et al., "Intercellular Communication Mediates the Bystander Effect During Herpes Simplex Thymidine Kinase/Ganciclovir-Based Gene Therapy of Human Gastrointestinal Tumor Cells", <i>Human Gene Therapy</i> , 9:719-728 (20 Mar 1998)
	AK	U.S. Patent Application Serial No. 08/974,549, "Human Telomerase Catalytic Subunit", filed 19 Nov 1997

Examiner	Date Considered

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 PTO-1449 — Page 3

<b>Form 1449</b> (modified)  <b>Information Disclosure</b>  <b>Statement By Applicant</b>  (Use Several Sheets if Necessary)	Docket: 019/246P Supplemental S.S.N. 09/244,438  Title: Telomerase Reverse Transcriptase Transcriptional Regulatory Sequences Inventors: Morin, G., et al.  Filing Date: 04 Feb 1999      Group: 1642
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**Foreign Patent or Published Foreign Patent Application**

Examiner Initial	Ref.	Document No.	Publ. Date	Jurisdiction	Title:	Translation	
						Yes	No
	A	GB 2317891	4/8/98	UK	hTERT, the reverse transcriptase subunit of human telomerase		

Examiner	Date Considered

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 PTO-1449 — Page 1

<b>Form 1449</b> (modified)  <b>Information Disclosure</b>  <b>Statement By Applicant</b>  (Use Several Sheets if Necessary)	Docket: 019/246P Suppl. U.S.N. 09/244,438  Title: TELOMERASE PROMOTER DRIVING EXPRESSION OF THERAPEUTIC GENE SEQUENCES Inventors: Morin, et al.  Filing Date: 04 February 1999      Group: 1635
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**U.S. Patent Documents**

Examiner Initial	Ref.	Patent No.	Filing Date	Issue Date	Class/ Subclass	Inventors:	Title:
	BA	5,907,083	Mar 18/96	May 25/99	800/205	Robert et al.	Brassica Sp. Gene Promoter Highly Expressed During Stigma Development
	BB	6,054,575	Dec 24/97	Apr 25/00	536/24.31	Villeponteau et al.	Mammalian Telomerase RNA Gene Promoter
	BC	6,228,643	Mar 22/97	May 8/01	435/419	Greenland et al.	Promoter
	BD	6,274,790	Apr 10/98	Aug 14/01	800/287	Kunst et al.	Nucleic Acids Encoding a Plant Enzyme Involved in Very Long Chain Fatty Acid Synthesis
	BE	6,281,409	Nov 4/96	Aug 28/01	800/287	Woodhead et al.	Blackcurrent Promoters and Genes
	BF	6,300,095	Mar 5/98	Oct 9/01	435/69.1	Barredo Fuente et al.	Promoters of the Genes Glutamate Dehydrogenase $\beta$ -N-Acetylhexosaminidase and $\gamma$ -Actin and Their Use in Filamentous Fungi Expression, Secretion and Antisense Systems
	BG	6,306,656	Oct 13/99	Oct 23/01	435/419	Liu et al.	Plant Embryo—and Aleurone—Specific Promoter
	BH	6,331,527	Nov 1/99	Dec 18/01	514/44	Parmacek et al.	Promoter Smooth Muscle Cell Expression

**Foreign Patent or Published Foreign Patent Application**

Examiner Initial	Ref.	Document No.	Publ. Date	Juris-diction	Title:	Translation
None						

**Other Documents**

Examiner Initial	Ref.	Author, Title, Date, Source
None		

Examiner	Date Considered

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 PTO-1449 — Page 1

<b>Form 1449 (modified)</b>  <b>Information Disclosure Statement By Applicant</b>  (Use Several Sheets if Necessary)	Docket: 019/246  Title: Telomerase Promoter Driving Expression of Therapeutic Gene Sequences Inventors: Gregg Morin et al.  Filing Date: February 4, 1999 Group: 1635
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**U.S. Patent Documents**

Examiner Initial	Ref.	Patent No.	Filing Date	Issue Date	Class/ Subclass	Inventors:	Title:
(none)							

**Foreign Patent or Published Foreign Patent Application**

Examiner Initial	Ref.	Document No.	Publ. Date	Jurisdiction	Title:	Translation	
						Yes	No
	CA	WO 00/46355	Aug 10/00	PCT	Telomerase Reverse Transcriptase Transcriptional Regulatory Sequences		

**Other Documents**

Examiner Initial	Ref.	Author, Title, Date, Source
	CB	Majumdar et al. The telomerase reverse transcriptase promoter drives efficacious tumor suicide gene therapy while preventing hepatotoxicity encountered with constitutive promoters. Gene Therapy 8:568, 2001.
	CC	Koga et al. A novel telomerase-specific gene therapy: Gene transfer of caspase-8 utilizing the human telomerase catalytic subunit gene promoter. Hu. Gene Ther. 11:1397, 2000.
	CD	Gu et al. Tumor-specific transgene expression from the human telomerase reverse transcriptase promoter enables targeting of the therapeutic effects of the Bax gene to cancers. Cancer Res. 60:5339, 2000.
	CE	Komata et al. Treatment of malignant glioma cells with the transfer of constitutively active Caspase-6 using the human telomerase catalytic subunit (human telomerase reverse transcriptase) gene promoter. Cancer Res. 61:5796, 2001.
	CF	Geron Corporation Press Release.. Geron Corporation and Genetic Therapy, Inc. partner to develop cancer therapy. January 7, 2002.

Examiner	Date Considered

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 PTO-1449 — Page 1

<b>Form 1449</b> (modified)  <b>Information Disclosure Statement By Applicant</b>  (Use Several Sheets if Necessary)	Docket: 019/246P  U.S.S.N. 09/244,438  Telomerase Reverse Transcriptase Transcriptional Regulatory Sequences Morin, G., et al.  Filing Date: 04 Feb 1999      Group: 1632
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**U.S. Patent Documents**

Examiner Initial	Ref.	Patent No.	Filing Date	Issue Date	Class/ Subclass	Inventors:	Title:
(NONE)							

**Foreign Patent or Published Foreign Patent Application**

Examiner Initial	Ref.	Document No.	Publ. Date	Juris-diction	Title:	Translation
	L1	WO 99/33998	8 Jul 1999	PCT	Regulatory DNA Sequences of the Human Catalytic Telomerase Sub-Unit Gene, Diagnostic and Therapeutic Use Thereof	Abstract
	L2	WO 99/33998	8 Jul 1999	PCT	<i>PARTIAL ENGLISH TRANSLATION:</i> Regulatory DNA Sequences of the Human Catalytic Telomerase Sub-Unit Gene, Diagnostic and Therapeutic Use Thereof	Partial

**Other Documents**

Examiner Initial	Ref.	Author, Title, Date, Source
(NONE)		

Examiner	Date Considered

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 PTO-1449 — Page 1

<b>Form 1449</b> (modified)  <b>Information Disclosure Statement By Applicant</b>	Docket: 019/246  Title: TELOMERASE PROMOTER DRIVING EXPRESSION OF THERAPEUTIC GENE SEQUENCES Inventors: Gregg B. Morin et al.  Filing Date: February 4, 1999	U.S.S.N. 09/244,438  Group: 1635 Examiner: Richard A. Schnizer, Ph.D.

**U.S. Patent Documents**

Examiner Initial	Ref.	Patent No.	Filing Date	Publish Date	Class/ Subclass	Inventors:	Title:
	DA	6,610,839	Sep 29/99	Aug 26/03	536/024.1; 435/194; 435/320.1	Morin et al.	Promoter for telomerase reverse transcriptase (cover & claims)
	DB	6,610,839	Sep 29/99	Aug 26/03	536/024.1; 435/194; 435/320.1	Morin et al.	Promoter for telomerase reverse transcriptase (specification)

**Foreign Patents and Published Foreign Patent Applications**

Examiner Initial	Ref.	Document No.	Publish Date	Jurisdiction	Title:	Translation
(None)						

**Other Documents**

Examiner Initial	Ref.	Author, Title, Date, Source
		(None)

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Page 1